K02 1669

JUN 5 2002

ADMINISTRATIVE INFORMATION

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories A Philips Medical Systems Company
540 Alder Drive
Milpitas, California 95035

Tel: (408) 468-3051
Fax: (408) 468-3050

Contact Person: Coleen Coleman
At address above

B. Device Trade Name: Physician's Desktop Review
Common Name: Picture Archive and Communication Systems (PACS)
Classification Name: Image Processing System

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	Pegasys Ultra™	K993946
ADAC Laboratories	Pegasys InTouch (WebView™)	K974474

D. Device Description:

Physician's Desktop Review (PDT) is a Windows®-based physician workstation. The product's design and features improve physician workflow by integrating image and information into his/her desktop environment. The comprehensive tools and features provided with this product allow the physician to review, interpret, and report results and not have to leave the office environment. The connectivity package allows the physician to download image data to his/her location reducing the time for travel and improving turn-around time for patient results.

E. Indications for Use:

Physician's Desktop Review is a medical image display workstation that provides software applications used for review and interpretation of medical images/data. The results obtained may be used as a tool in interpretation of data derived from any medical imaging procedures. The Physician's Desktop Review system should only be operated by qualified

healthcare professionals (e.g., radiologists, cardiologists, oncologists, or general nuclear medicine physicians) trained in the use of medical imaging equipment.

F. Technological Comparison:

The Physician's Desktop Review, Pegasys Ultra™ (K993946), and Pegasys InTouch (WebView™) (K974474) have similar indications for use and overall function and perform in a similar manner with respect to, display, review applications, data storage, and system utilities.

II. CONCLUSION

Physician's Desktop Review is substantially equivalent to the predicate devices the Pegasys Ultra™ (K993946) and InTouch (Webview™ K974474) based on similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2002

ADAC Laboratories
% Ms. Elizabeth Drew
Reviewer
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K021669
Trade/Device Name: Physician's Desktop Review
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 17, 2002
Received: May 21, 2002

Dear Ms. Drew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K02 1669

Device Name: Physician's Desktop Review

Sponsor Name: ADAC Laboratories A Philips Medical Systems Company

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021669

Prescription Use ☑
Over-The-Counter Use ☐